

HIPAA Form

Prospective, Randomized, Single Blind Clinical Trial to Investigate the Impact of Autologous Bone Marrow Concentrate in Knee Osteochondral Allograft Transplantation

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ORA # 17121805

Rush University Medical Center

AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION IN RESEARCH

Name of the Research Study: Prospective, Randomized, Single Blind Clinical Trial to Investigate the Impact of Autologous Bone Marrow Concentrate in Knee Osteochondral Allograft Transplantation

Name of Principal Investigator: Brian J. Cole, MD, MBA and Adam B. Yanke, MD

The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research. The word “we” refers to Rush University Medical Center, its employees and affiliates, including the study doctor and his/her research staff. You will be asked to sign this form along with the attached research consent form.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. Some of this information may come from results of tests, procedures, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information is described in the attached consent form.

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We may keep the information forever, in case we need to look at it again for this research study.

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

This study is considered a “blinded study”, which means that the researcher is asking you to accept one of several drugs or treatments, without knowing exactly which one you are being given. Therefore, the researcher may not be able to let you know which drug or treatment you are being given at any that point in the study except in case of emergency. We cannot do the research if you do not agree to let the researcher hold back this information until the time listed below. You have the right to request to see your records after the study is completed.

- What blinded drugs or treatments are offered?
 - During your scheduled knee surgery, you will be randomly assigned to either have bone marrow taken from your iliac crest (hip bone) and re-injected into your injured knee or to have a regular knee surgery with a sham incision over your hip, no bone marrow taken from your iliac crest and no bone marrow cells used.
- When (in weeks from the start of the study, or as a date) will you be told about the specific drug or treatment that you were given?
 - You will be told about the specific treatment that you were given at the end of the study. This will be approximately 2 years from your original surgery.

If you sign this form, you are giving us permission to collect, use, and share your health information.

You do not have to sign this form. If you decide to NOT sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher listed above. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. If we cannot collect and share your health information, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

If you sign this form, we may continue to share the health information collected for this study with the people listed in the Confidentiality section, without any time limit, unless you withdraw your authorization. This authorization does not expire.

CONFIDENTIALITY

We may share your information with people who help with the research. Some of these people may be other researchers outside of the hospital or are in charge of the research, pay for or work with us on the research. Some of these people make sure we do the research properly. Some of these people may share your information with someone else. If they do, the same laws that Rush must obey may not protect your health information. For this study, we will share information with:

If your information is transferred outside of the United States, different privacy laws may apply. Additionally, if one of the companies or institutions listed above merges with, or is purchased by, another company or institution, this authorization to use and disclose protected health information in the research will extend to the successor company or institution.

If you have any questions, please ask the researcher or his/her staff. Their phone numbers appear in the attached consent form. You can also call 1-800-876-0772 at Rush with general questions about your rights and the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The health information about _____ can be collected and used by the researchers and staff for the research study described in this form and the attached consent form.

Signature: _____

Date: _____

Print name: _____

Legal authority: _____
